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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/662,757
Filing Date: September 15, 2003
Appellant(s): WILLIAMS ET AL.

Needham James Boddie, II
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 1, 2008 appealing from the Office action mailed February 12, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is *substantially* correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Claims 86 and 98 as rejected under 35. U.S.C. 103(a) as being unpatentable over EP 0405284 to Greiner are withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 02/43799	Igaki et al.	6-2002
6,251,136	Guruwaiya et al.	6-2001
EP 0405284	Greiner	1-1991
6,670,398	Edwards et al.	12-2003
WO 01/87368	Mehta et al.	11-2001
6,299,604	Ragheb et al.	10-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 73-74, 76, 80-84, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/43799 to Igaki et al. (hereinafter "Igaki"; references are made to the English translation filed herewith).

Igaki discloses a method of impregnating a stent with a pharmacological agent (abstract), the method comprising:

immersing a stent comprising a polymeric material in a mixture of a carrier fluid and a pharmacological agent (fourth full paragraph on pg. 11);

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the polymeric material (fourth full paragraph on pg. 12);

removing the pressure such that the carrier fluid diffuses out of the polymeric material (first full paragraph on pg. 14) and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material (second full paragraph on pg. 4).

The polymeric layer is only a single layer and, thus, is interpreted to be a non-layered polymeric material.

Igaki teaches that the removal of the pressure involves the opening of a valve to gradually exhaust the carrier fluid (first full paragraph on pg. 14), but does not explicitly teach that the pharmacological agent becomes elutably trapped within the polymeric material in a

predetermined concentration gradient due to the removal of the pressure under controlled conditions. However, Igaki teaches that the pressure is gradually exhausted (i.e., removing the pressure over a predetermined period of time) in a reaction chamber (i.e., under controlled conditions) and, thus, teaches all the steps as claimed. Because the method of Igaki is so similar to the claimed steps, the two methods must necessarily achieve similar results. Unless critical steps are missing from the claims, the pharmacological agent must necessarily have some sort of concentration gradient within the polymeric material in the method of Igaki. This concentration gradient, therefore, must necessarily define an elution profile of the pharmacological agent, as required in the claims. Additionally, the predetermined concentration gradient can be zero.

Claim 74: The pressure and rate of pressure change is controlled during the step of removing the pressure.

Claims 76,80: Supercritical carbon dioxide is the carrier fluid (first full paragraph to fourth full paragraph on pg. 12).

Claims 81,83: The carbon dioxide can contain a co-solvent, such as ethanol (fifth paragraph on pg. 11).

Claim 82: The carrier fluid is used to cause the polymer to become swollen (second full paragraph on pg. 14), thereby altering the diffusion coefficients of the polymeric material.

Claim 84: The intraluminal prosthesis is a stent (first paragraph on pg. 2).

Claim 86: The polymeric material can be formed only on the surface of the stent (first full paragraph on pg. 4).

Claims 75, 99-101, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,251,136 to Guruwaiya et al. (hereinafter "Guruwaiya").

Igaki is discussed above, but does not explicitly teach the step of masking the stent. However, Guruwaiya teaches a method of coating a pharmacological agent on a stent (abstract), wherein certain portions of the stent are masked during the coating process. The mask is used to selectively coat the stent in order to achieve a specific effect when using the stent for its intended purpose (col. 2, lines 49-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have masked certain portions of the stent of Igaki with a reasonable expectation of success. One would have been motivated to do so in order to have

achieved a specific effect as described in Guruwaiya. The mask is then removed after the coating of the pharmacological agent because the mask is not part of the final product.

Claim 99: Igaki does not explicitly teach impregnating with first and second pharmacological agents at first and second unmasked portions. Guruwaiya teaches that two different portions of the stent can be coated with two different pharmacological agents (col. 4, lines 58-62), thus requiring a first masking step to apply the first pharmacological agent and a second masking step to apply the second pharmacological agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have masked first and second portions and to have applied a first and second pharmacological agent to the unmasked regions of Igaki in order to have manufactured a stent having two different effects.

Claim 100: Igaki teaches that the pressure and rate of pressure change is controlled during the step of removing the pressure.

Claims 101,104: Igaki teaches that the carrier fluid can be supercritical carbon dioxide.

Claims 73-74, 76-78, 80-82, 86, 88-89, 91-93, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0405284 to Greiner (hereinafter "Greiner").

Examiner notes that the rejection to claims 86 and 98 are being withdrawn.

Greiner teaches a method of impregnating a catheter with a pharmacological agent (col. 2, lines 33-35). The catheter is placed in a pressure vessel. The pharmacological agent is added to the reactor and carbon dioxide (i.e., a carrier fluid) is used to pressurize the reactor. The reactor is then cooled and depressurized (Example 1). The pharmacological agent has at least partially penetrated and become impregnated into the polymeric material (col. 3, lines 23-27). The polymeric material forms a single layer and, thus, is interpreted to be a non-layered polymeric material.

Greiner teaches that the reactor is depressurized after impregnating (col. 4, lines 2-6; col. 5, lines 18-25), but does not explicitly teach that the pharmacological agent becomes elutably trapped within the polymeric material in a predetermined concentration gradient due to the removal of the pressure under controlled conditions. However, Greiner teaches that the pressure is lowered (i.e., removing the pressure over a predetermined period of time) in a reactor (i.e., under controlled conditions) and, thus, teaches all the steps as claimed. Because the method of

Greiner is so similar to the claimed steps, the two methods must necessarily achieve similar results. Unless critical steps are missing from the claims, the pharmacological agent must necessarily have some sort of concentration gradient within the polymeric material in the method of Greiner. This concentration gradient, therefore, must necessarily define an elution profile of the pharmacological agent, as required in the claims. Additionally, the predetermined concentration gradient can be zero.

Claims 77-78,81,88,93: Greiner does not explicitly teach that the reactor is pressurized with an inert gas consisting of helium, nitrogen, and argon. However, Greiner does exemplify both carbon dioxide and nitrogen as preferred and suitable carrier fluids (col. 3, lines 12-22). One of ordinary skill in the art would have expected that using a combination of suitable carrier fluids (i.e., using both carbon dioxide and nitrogen) as taught by Greiner to have similar results as just using carbon dioxide alone. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used carbon dioxide along with nitrogen gas, instead of just using carbon dioxide alone, in the method of Greiner with a reasonable expectation of success because Greiner teaches that both gases are suitable carrier fluids and because one of ordinary skill in the art would have expected similar results when using a combination of carrier fluids as opposed to using only a single carrier fluid.

Claims 74,89: The pressure is lowered in the reactor (col. 4, lines 2-6). There must be some control of how fast the rate of pressure changes.

Claims 76,80,91-92: The carrier fluid can be supercritical carbon dioxide (col. 3, lines 12-27).

Claim 82: The supercritical carbon dioxide causes the intraluminal prosthesis to swell, thereby causing a more complete diffusion of the pharmacological agent (col. 3, lines 23-29).

Claims 75, 90, and 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner as applied to claim 78 above, in view of Guruwaiya.

Greiner is discussed above, but does not explicitly teach the step of masking the catheter. However, Guruwaiya teaches a method of coating a pharmacological agent on a medical device (abstract), wherein certain portions of the medical device are masked during the coating process. The mask is used to selectively coat the medical device in order to achieve a specific effect when

using the medical device for its intended purpose (col. 2, lines 49-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have masked certain portions of the catheter of Greiner with a reasonable expectation of success. One would have been motivated to do so in order to have achieved a specific effect as described in Guruwaiya. The mask is then removed after the coating of the pharmacological agent because the mask is not part of the final product.

Claim 99: Greiner does not explicitly teach impregnating with first and second pharmacological agents at first and second unmasked portions. However, Guruwaiya teaches that two different portions of the medical device can be coated with two different pharmacological agents (col. 4, lines 58-62), thus requiring a first masking step to apply the first pharmacological agent and a second masking step to apply the second pharmacological agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have masked first and second portions and to have applied a first and second pharmacological agent to the unmasked regions of Greiner in order to have manufactured a stent having two different effects.

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki as applied to claim 73 above, and further in view of U.S. Patent 6,670,398 to Edwards et al. (hereinafter "Edwards").

Igaki is discussed above, but does not teach the use of everolimus as the pharmacological agent. However, Edwards teaches everolimus is a therapeutic drug that can be used to suppress the transplant recipient's immune response against a transplanted organ or tissue (col. 2, lines 3-10). Everolimus can be coated onto a stent (col. 21, lines 8-39). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have impregnated everolimus as the particular pharmacological agent onto the stent of Igaki with a reasonable expectation of success because Edwards teaches that it is suitable to administer everolimus using a stent and because one would have been motivated to do so in order to provide stent for use in organ or tissue transplant.

Claims 79 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner as applied to claims 73 and 88 above, and further in view of Edwards.

Greiner does not explicitly teach the use of everolimus. However, Greiner is open to the use of other pharmacological agents (col. 4, lines 7-29). Accordingly, Edwards teaches everolimus is a therapeutic drug that can be used to suppress the transplant recipient's immune response against a transplanted organ or tissue (col. 2, lines 3-10). Everolimus can be coated onto a medical device (col. 21, lines 8-39). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have impregnated everolimus as the particular pharmacological agent onto the catheter of Greiner with a reasonable expectation of success. One would have been motivated to do so in order to provide a catheter for use in organ or tissue transplant.

Claims 85 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner as applied to claim 73 above, and further in view of WO 01/87368 to Mehta et al. (hereinafter "Mehta").

Greiner is discussed above, but does not explicitly teach the polymeric material can be non-erodible. However, Greiner does teach the desire to control the release of the drug into the target site (col. 4, lines 39-41). Mehta teaches a method of making a stent, wherein the stent is coated with a polymer and a pharmacological agent (pg. 7, lines 12-29). The polymeric material can be either biostable (i.e., non-erodible) or bioabsorbable (i.e., erodible) depending on the desired rate of release (pg. 8, lines 9-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a biostable polymer in the process of making the stent of Greiner. One would have been motivated to do so in order to have controlled the rate of release of the pharmacological agent.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki as applied to claim 73 above, and further in view of U.S. Patent 6,299,604 to Ragheb et al. (hereinafter, "Ragheb").

Igaki and Guruwaiya are discussed above. Igaki teaches heparin as an example of a pharmacological agent (second full paragraph on pg. 11), but does not explicitly teach using a radiopaque material. However, Ragheb teaches that a radiopaque material is a suitable alternative to heparin for use in the vascular system (col. 3, line 54-col. 4, line 10). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a radiopaque material as the particular pharmacological agent with a reasonable expectation of success because Ragheb teaches that radiopaque materials are suitable pharmacological agents that can be used in the vascular system.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner as applied to claim 73 above, and further in view of Ragheb.

Greiner teaches vasodilators as an example of a pharmacological agent (col. 4, lines 7-13), but does not explicitly teach using a radiopaque material. However, Ragheb teaches that a radiopaque material is a suitable alternative to vasodilators for use in the vascular system (col. 3, line 54-col. 4, line 10). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Because Ragheb teaches that such pharmacologic agents are operable for use in medical devices, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a radiopaque material as the particular pharmacological agent of Greiner with a reasonable expectation of success.

Claims 81, 83-84, 86, 93-94, 96, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner as applied to claims 88 above, and further in view Igaki.

Claims 81,83,93-94: Greiner is discussed above, but does not explicitly teach that a co-solvent consisting of the group of ethanol and methanol can be used with the carbon dioxide.

However, Igaki teaches that a co-solvent such as ethanol can be added to the carbon dioxide to increase the impregnation of the pharmacological agent (fifth paragraph on pg. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have added ethanol to the carbon dioxide of Greiner with a reasonable expectation of success. One would have been motivated to do so in order to have increased the impregnation of the pharmacological agent.

Claims 84,86,96,98: Greiner does not explicitly teach that the intraluminal prosthesis can be used as a stent. Greiner only teaches that above-discussed method can be used for a catheter. However, Igaki teaches a similar process for impregnating a stent for similar purposes and, thus, one of ordinary skill in the art would have expected similar results for impregnating a stent as compared to impregnating a catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have impregnated a stent, as opposed to a catheter, using the method of Greiner with a reasonable expectation of success because Igaki teaches a similar process can be performed on stents to achieve similar results.

(10) Response to Argument

II. Claims 73, 74, 76, 80-84 and 86 are patentable over U.S. Patent Publication No. 2003/0104030 to Igaki et al.

Claims 73-74, 76, 80-84, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/43799 to Igaki et al. (hereinafter "Igaki").

Examiner notes that the claims were rejected over WO 02/43799 while references were made to the English equivalent U.S. Publication No. 2003/0104030. A human translation of the WO 02/43799 patent is provided herewith. References will be made to the translation.

A. Independent Claim 73

Appellants argue on pg. 8-9 of the Brief:

> Thus, a full and fair reading of paragraph 0062 of Igaki fails to show that the steps of Igaki result in a concentration gradient in the polymeric material as taught by the present invention but rather describes a process in which a stent is "fully impregnated" with the drug.

A concentration gradient in the polymeric material of Igaki would still have occurred due to the inherency of the process. For example, the present specification teaches in the paragraphs bridging pg. 16-17:

> The step of removing pressure is carried out under controlled conditions after a predetermined time and according to a predetermined schedule to insure that the desired predetermined amount of the pharmacological agent remains. Controlled conditions include controlling one or more of the following parameters in a predetermined pattern: temperature, rate of temperature change, pressure, **rate of pressure change**, carrier fluid quantity, concentration of the pharmacological agent in the carrier fluid, concentration of cosolvents and surfactants etc. These parameters can control the concentration of the pharmacological agent entrapped within the polymeric material after depressurization has been achieved. Moreover, **as these parameters are varied, concentration gradients of the pharmacological agent entrapped within the polymeric material after depressurization can be achieved.**
> (emphasis added)

Igaki teaches that the supercritical CO_2 pressure within the reaction chamber 27 is gradually discharged to bring the chamber to atmospheric pressure (first full paragraph on pg. 14). The rate of pressure change is controlled in the process of Igaki since the pressure is "gradually" released. Because a concentration gradient is created in the present invention when the rate of pressure change is controlled, such a phenomenon must also necessarily occur in the method of Igaki due to the controlled release of the pressure. "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established" (MPEP 2112.01.I.). Thus, the method of Igaki inherently forms a concentration gradient in the polymeric layer.

Appellants argue on pg. 10-11 of the Brief that there is no evidence that the claimed methods necessarily flow from the teachings of the cited art and therefore the claimed methods of this invention cannot be obvious as inherent in the teachings of Igaki. However, the evidence of inherency comes from the present specification where a process similar to the process of Igaki is performed. Unless some critical steps are missing from the claims, the process of Igaki must necessarily achieve similar results to that of the claimed invention. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the

authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

Appellants argue on pg. 11 of the Brief that the only method in Igaki for controlling the release time point and quantity of an impregnated drug is via the use of layers of biodegradable polymer material and not via a concentration gradient. Although Igaki intended to use additional layers to release large quantities in a short time or to delay the release of the drug (first full paragraph on pg. 16), the method of Igaki would still necessarily create a concentration gradient, as discussed above.

Appellants argue on pg. 11-12 of the Brief that the term gradient is defined as "the rate of regular or graded ascent or descent" and that a "concentration gradient" is defined as "a gradual change in the concentration of solutes in a solution as a function of distance through a solution". Appellants further argue that a concentration can be zero, but a gradient by definition cannot be zero. However, gradient is a measure of a rate of change, which can be zero. For example, a flat road can have a gradient of zero degrees because the rate at which the flat road changes altitude is zero. The rate of change of velocity, length, temperature, and any other unit can be zero. Thus, a concentration gradient (i.e., the rate of change of concentration) in the polymeric layer Igaki can be interpreted to be zero.

B. Dependent Claim 86

Appellants argue on pg. 12-13 of the Brief that there is no teaching or suggestion in Igaki that the polymeric material is a coating on a portion of the intraluminal prosthesis. However, Igaki teaches that "[i]n methods to **cover the metal stent using a polymer sheet**, it is necessary to prepare the polymer sheet containing the drug agent under high temperature conditions, leading to concerns of a loss in the effectiveness of the drug agent" (emphasis added) (first full paragraph on pg. 4). Thus, the polymeric material at least covers a portion of the metal stent.

III. Claims 73, 74, 76-78, 80-82, 86, 88, 89, 91-93 and 98 are patentable over European Patent No. EP 0405284 to Greiner.

Claims 73-74, 76-78, 80-82, 86, 88-89, 91-93, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0405284 to Greiner (hereinafter "Greiner").

A. Independent Claim 73

Appellants argue on pg. 14 of the Brief that Greiner does not describe removing the pressure over a predetermined time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. However, as noted by Appellants, Greiner teaches that the pressure is lowered (col. 4, lines 2-6) and that the reactor is depressurized after the impregnating step (col. 5, lines 18-25). The pressure must necessarily be released at some rate in order to lower the pressure in the chamber, resulting in a rate of pressure change within the chamber. The pressure is lowered in some predetermined manner and, thus, the rate of release must necessarily be controlled to some degree. Because a concentration gradient is created in the present invention when the rate of pressure change is controlled and unless critical steps are missing, such a phenomenon must also necessarily occur in the method of Greiner due to the controlled release of the pressure.

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established" (MPEP 2112.01.I.). Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

Additionally, the removal of the volatile swelling agent from the catheter would result in a concentration gradient. The catheter is immersed "in a saturated solution containing the pharmaceutical dissolved in a highly volatile, pharmaceutically acceptable solvent capable of swelling the polymer materials" (col. 3, lines 3-11). "After contacting, the volatile swelling agent is separated from the catheter, leaving the pharmaceutical behind. Because of the volatility of the swelling agents employed, separation is easily accomplished by lowering the pressure" (col. 4, lines 2-6). Both the volatile swelling agent and the pharmaceutical penetrate into the

polymeric material of the catheter during the impregnating step. Upon releasing the pressure, the volatile swelling agent escapes from the polymeric material. Because the volatile swelling agent dissolves the pharmaceutical, the volatile swelling agent would dissolve some of the pharmaceutical impregnated in the catheter when the volatile swelling agent is removed from the catheter. The volatile swelling agent moves in the direction toward the outer surface of the polymeric material as it escapes. The portions of the polymeric material towards the outer surface would be exposed to more of the escaping volatile swelling agent than the portions further away from the outer surface, thus causing more of the pharmaceutical to be dissolved and carried away at the portions of the polymeric material towards the outer surface. This would cause the pharmaceutical to be less concentrated at the outer surface of the polymer and more concentrated at the portions of the polymer further away from the outer surface. Therefore, the reduction of pressure to remove the volatile swelling agent would necessarily result in a concentration gradient in the catheter.

B. Dependent Claim 86

Appellants' arguments on pg. 15 of the Brief are convincing. The rejection of Claim 86 is being withdrawn.

C. Independent Claim 88

Appellants argue on pg. 16 of the Brief that Greiner fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. However, the process of Greiner would necessarily result in a concentration gradient of the pharmaceutical in the polymeric material, as discussed above (see section IIIA).

D. Dependent Claim 98

Appellants' arguments on pg. 17 of the Brief are convincing. The rejection of Claim 98 is being withdrawn.

IV. Claims 75, 99-101 and 104 are patentable over U.S. Patent Publication No. 2003/0104030 to Igaki et al. in view of U.S. Patent No. 6,251,136 to Guruwaiya

Claims 75, 99-101, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,251,136 to Guruwaiya et al. (hereinafter "Guruwaiya").

A. Dependent Claim 75

Appellants argue on pg. 17-18 of the Brief that Igaki fails to teach or suggest all of the recitations of independent Claim 73, and Guruwaiya fails to remedy the deficiencies of Igaki. However, Igaki teaches all the limitations of Claim 73, as discussed above (see section IIA).

B. Independent Claim 99 and dependent Claims 100, 101 and 104

Appellants argue on pg. 18-20 of the Brief that Igaki fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. Appellants additionally argue that Guruwaiya fails to remedy the deficiencies of Igaki. However, Igaki teaches all the limitations of the claims for substantially the same reasons as discussed above for Claim 73 (see section IIA).

V. Claims 75, 90 and 99-104 are patentable over European Patent No. EP 0405284 to Greiner in view of U.S. Patent No. 6,251,136 to Guruwaiya

Claims 75, 90, and 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Guruwaiya.

A. Dependent Claim 75

Appellants argue on pg. 20-21 of the Brief that Greiner fails to teach or suggest all of the recitations of independent Claim 73 and that Guruwaiya fails to remedy the deficiencies of Greiner. However, Greiner teaches all of the limitations in Claim 73, as discussed above (see section IIIA).

B. Dependent Claim 90

Appellants argue on pg. 21 of the Brief that Greiner fails to teach or suggest all of the recitations of independent Claim 88 and that Guruwaiya fails to remedy the deficiencies of Greiner. However, Greiner teaches all of the limitations in Claim 88, as discussed above (see section IIIC).

B. Independent Claim 99 and dependent Claims 100-104

Appellants argue on pg. 21-22 of the Brief that Greiner fails to teach or suggest removing the pressure over a predetermined period of time and under controlled conditions such that the carrier fluid diffuses out of the non-layered polymeric material and the pharmacological agent becomes elutably trapped within the non-layered polymeric material in a predetermined concentration gradient. Appellants additionally argue that Guruwaiya fails to remedy the deficiencies of Greiner. However, Greiner teaches all the limitations of the claims for substantially the same reasons as discussed above for Claim 73 (see section IIIA).

VI. Claim 79 is patentable over U.S. Patent Publication No. 2003/0104030 to Igaki et al. in view of U.S. Patent No. 6,670,398 to Edwards

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki in view of U.S. Patent 6,670,398 to Edwards et al. (hereinafter "Edwards").

Appellants argue on pg. 23 of the Brief that Igaki fails to teach or suggest all of the recitations of independent Claim 73 and that Edwards fails to remedy the deficiencies of Igaki. However, Igaki teaches all the limitations of Claim 73, as discussed above (see section IIA).

VII. Claims 79 and 95 are patentable over European Patent No. EP 0405284 to Greiner in view of U.S. Patent No. 6,670,398 to Edwards

Claims 79 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Edwards.

Appellants argue on pg. 23-24 of the Brief that Greiner fails to teach or suggest all of the recitations of independent Claims 73 and 88 and that Edwards fails to remedy the deficiencies of Greiner. However, Greiner teaches all of the limitations in Claims 73 and 88, as discussed above (see sections IIIA and IIIC).

VIII. Claims 85 and 97 are patentable over European Patent No. EP 0405284 to Greiner in view of PCT Publication WO 01/87368 to Mehta

Claims 85 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of WO 01/87368 to Mehta et al. (hereinafter "Mehta").

Appellants argue on pg. 24 of the Brief that Greiner fails to teach or suggest all of the recitations of independent Claims 73 and 88 and that Mehta fails to remedy the deficiencies of Greiner. However, Greiner teaches all of the limitations in Claims 73 and 88, as discussed above (see sections IIIA and IIIC).

IX. Claim 87 is patentable over U.S. Patent Publication No. 2003/0104030 to Igaki et al. in view of U.S. Patent No. 6,299,604 to Ragheb

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki in view of U.S. Patent 6,299,604 to Ragheb et al. (hereinafter, "Ragheb").

Appellants argue on pg. 24-25 of the Brief that Igaki fails to teach or suggest all of the recitations of independent Claim 73 and that Ragheb fails to remedy the deficiencies of Igaki. However, Igaki teaches all the limitations of Claim 73, as discussed above (see section IIA).

X. Claim 87 is patentable over European Patent No. EP 0405284 to Greiner in view of U.S. Patent No. 6,299,604 to Ragheb

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner in view of Ragheb.

Appellants argue on pg. 25 of the Brief that Greiner fails to teach or suggest all of the recitations of independent Claim 73 and that Ragheb fails to remedy the deficiencies of Greiner. However, Greiner teaches all of the limitations in Claim 73, as discussed above (see section IIIA).

XI. Claims 81, 83, 84, 86, 93, 94, 96 and 98 patentable over European Patent No. EP 0405284 to Greiner in view of U.S. Patent Publication No. 2003/0104030 to Igaki et al.

Claims 81, 83-84, 86, 93-94, 96, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner '284 as applied to claims 88 above, and further in view Igaki '799.

Appellants argue on pg. 26 of the Brief that Igaki and Greiner fail to teach or suggest all of the recitations of independent Claims 73 and 88. However, Igaki and Greiner teach all the limitations of Claims 73 and 88, as discussed above (see sections IIA, IIIA and IIIC).

A. Dependent Claim 86

Appellants argue on pg. 26-27 of the Brief that there is no teaching or suggestion in either Igaki or Greiner that the polymeric material is a coating on a portion of the intraluminal prosthesis. However, Igaki teaches that "[i]n methods to cover the metal stent using a polymer sheet, it is necessary to prepare the polymer sheet containing the drug agent under high temperature conditions, leading to concerns of a loss in the effectiveness of the drug agent" (first full paragraph on pg. 4). Thus, Igaki teaches that the polymeric material at least covers a portion of the metal stent.

B. Dependent Claim 98

Appellants argue on pg. 27 of the Brief that there is no teaching or suggestion in either Igaki or Greiner that the polymeric material is a coating on a portion of the intraluminal prosthesis. However, Igaki does teach such a limitation, as discussed above (see section XIA).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jimmy Lin/
Examiner, Art Unit 1792

Conferees:

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1792

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